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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/731,499	10/16/1996	JOE W. GRAY	2500.124US1	6686

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2003

46

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/731,499

Applicant(s)

Gray et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6-19, 23, and 45-69 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-19, 23, and 45-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

1. The request filed on January 22, 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/731,499 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claim 68 and 69 have been added. Claims 1, 6-19, 23 and 45-69 are pending and under consideration

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

4. The disclosure is objected to because of the following informalities:

On page 1, in the cross-reference to related applications, the issued patent numbers of U.S. 5, 892,010 and 5,801,021, should be incorporated. Further, it should be stated that 08/680,395 is a continuation in part of 08/546,130 as the disclosures of the '395 application and the '130 application are not identical.

On page 29 line 29, the text reads "(e.g. @@ were overexpressed on various cancers). The significance of the "@@" is unclear.

Appropriate correction is required.

5. Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New claim 69 is drawn to the isolated nucleic acid of claim 1 wherein the labeled polynucleotide sequence comprises a biotin molecule, a dioxigenin moiety, a hapten or an antigenic protein. The specification on page 26 states that examples of labels which are indirectly detected are haptens and proteins for which labeled antisera or monoclonal antibodies are available. New claim 69 comprises all haptens and antigenic molecules without the qualification

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that labeled antisera or monoclonal antibodies be available, which is wider in scope than the haptens and proteins used as indirect labels as stated in the specification as originally filed.

6. Claims 1, 6, 8, 10, 12, 14, 16, 18, 45, 46, 47-61, 63, 64, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanner et al (Cancer Research, 1994, Vol. 54, pp. 4257-4260, reference A3 of the IDS filed April 15, 1997). Claim 1 is drawn to an isolated nucleic acid molecule comprising a labeled polynucleotide sequence that hybridizes under stringent conditions to a sequence or a complement of a sequence selected from the group consisting of SEQ ID NO:2, 3, 4, 5, 6, 7, 8, 9, and 10. Claims 6, 8, 10, 12, 14, 16 and 18 embody the isolated nucleic acid of claim 1 wherein said polynucleotide hybridizes to a complement of SEQ ID NO:4, 5, 6, 7, 8, 9 and 10, respectively. Claim 45 embodies the isolated nucleic acid of claim 1 wherein said nucleic acid has a length greater than about 50 nucleotides. Claim 46 specifies that the isolated nucleic acid molecule is a DNA molecule. Claim 47 is drawn to an isolated nucleic acid molecule comprising a promoter operably linked to a polynucleotide sequence selected from the group consisting of SEQ ID NO:2, 3, 4, 5, 6, 7, 8, 9, 10 and 12. Claims 48-57 embody the isolated nucleic acid of claim 47 wherein the promoter is operably linked to SEQ ID NO:2, 3, 4, 5, 6, 7, 8, 9, 10 and 12, respectively. Claim 58 is drawn to an isolated nucleic acid molecule comprising a polynucleotide sequence that hybridizes under stringent conditions to a sequence or a complement of a sequence selected from the group consisting of SEQ ID NO:2, 3 and 12. Claims 59-61 embody the nucleic acid sequence of claim 59 wherein the polynucleotide sequence hybridizes under stringent conditions to a complement of SEQ ID NO:2, 3, and 12, respectively. Claim 63 embodies the isolated nucleic acid sequence of claim 58 wherein the nucleic acid is labeled. Claim 64 is drawn to an isolated nucleic acid sequence comprising SEQ ID NO:9, 10 or 12. Claim 68 embodies the isolated nucleic acid of claim 1 wherein the labeled polynucleotide comprises a radioactive label, a fluorescent label, an electron dense reagent, a colorimetric label, or a magnetic

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label. Claim 69 embodies the isolated nucleic acid of claim 1, wherein the labeled polynucleotide comprises a biotin-moiety, a dioxigenin moiety, a hapten or an antigenic peptide.

Tanner et al disclose the cosmid probe RMC20C001 labeled with biotin which hybridized to the q13 region of chromosome 20. Tanner et al disclose that after hybridization the probe was detected by avidin-fluorescein isothiocyanate, thus fulfilling the specific embodiment of claim 68 with respect to a fluorescent label and claim 69 with respect to biotin. Tanner et al disclose that this cosmid defined the region of highest copy number in primary breast tumors (page 4259, under the heading "Analysis of Primary Breast Cancers"). The instant specification states on page 3, lines 20-21, that SEQ ID NO:1-10 and 12 are nucleic acid sequences within the 20q13 amplicon. Thus, SEQ ID NO:2-10 and 12 would be comprised within the cosmid, and the cosmid would hybridize under stringent conditions to SEQ ID NO:2-10 and 12 or the complements of SEQ ID NO:2-10 and 12. Further, the cosmid is a genomic sequence and would comprise promoters operably linked to the open reading frames of individual genes within the 20q13 amplicon, thus anticipating claims 47-57.

7. Claims 58-61 are rejected under 35 U.S.C. 102(b) as being anticipated by The New England Biolabs Catalog (1993-1994, page 91, cited in a previous Office action). The specific embodiments of claims 58-61 are recited above. The New England Biolabs Catalog discloses Random Primers on page 91 which would hybridize under stringent conditions to SEQ ID NO:2, 3 and 12 or the complements of SEQ ID NO:2, 3, and 12.

8. The rejection of claims 1, 6-19, 23 and 45-67 under the judicially created doctrine of obviousness-type double patenting over claims 11-17 of USP 5,801,021 is maintained until the time that applicants file a terminal disclaimer.


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9. The rejection of claims 1, 6-13, 23, 45-53, 58-60 and 63 under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of USP 5,892,010 is maintained. The rejection is maintained until the time that applicants file a terminal disclaimer.

10. All other rejections and objections as set forth in Paper No. 38 are withdrawn.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 7, 2003